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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PAK, JOHN D	

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1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/891,256	LINDAHL, AKE R.	
	Examiner	Art Unit	
	John Pak	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/14/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-49 are pending in this application.

At the outset, a discussion as to pH is set forth so that a clearer understanding of the Examiner's position and applicant's position can be discerned.

(1) It is noted that the instant claims recite a step (d), wherein "adjusting the pH to 3.5 to 4.9" is required. This would ordinarily mean **adjusting the pH of the composition that is being made**, i.e. this does not raise any specific requirement as to storage pH or duration of stability. Applicant's specification is in agreement (spec. p. 5) (emphases added) –

> The composition can be formulated by combining the following components with water: a polycarboxylic acid having a chain length of 2 to 6 carbon atoms; a tin salt; salicylic acid or a salt of salicylic acid; and a monoglyceride of a fatty acid in crystaline form, to form a mixture. The solution is then heated to a temperature sufficient to dissolve the crystalline monoglycerides. The solution is cooled at a controlled rate to form crystals of the monoglyceride of a fatty acid and then the pH is adjusted to about 3.5 to about 4.9. It should be noted that unless otherwise mentioned pH values refers to determinations performed immediately after manufacture. Hydrogen peroxide can be added before or after cooling the mixture, as desired for the particular application.

(2) Additionally, applicant states that the pH rises during storage (spec. p. 6, lines 7-10), and "optimal pH during storage has been found to be from about 3.5 to about 4.9"

(spec. p. 6, lines 5-6). Therefore, applicant's specification contains somewhat contradictory pH and stability disclosure:

- Adjust pH to 3.5 to 4.9 after manufacture (claims & spec)
- Optimal pH during storage is about 3.5 to about 4.9
- pH rises during storage

So if pH rises during storage, adjusting to pH 4.9 will ensure the storage pH would be suboptimal. Similarly, adjusting to pH 3.5 as the low end of the pH range will miss out on having a storage pH of 3.5 since something lower than 3.5 is needed at the start of storage to obtain pH 3.5 during storage.

Applicant's specification Tables 1-3 have been reviewed. Compositions 6, 7 and 11 meet the current claim language scope. These compositions contain the following components:

	Compositions 6, 7, 11	Breath of the claims
Hydrogen peroxide	1.15%	**>0 to 2%**
1-glycerolmonolaurate (C12)	7%	1-35% monoglyceride(s) of
1-glycerolmonomyristate (C14)	21%	**fatty acid**
Myrj 59 (POE stearate)	**1%**	***not claimed***
Popylene glycol	**2%**	***only in claims 22, 44***
Sodium stannate	0.04%	0.005 to 0.05% any tin salt
Salicylic acid	0.1%	0.02 to 0.5%
Na pyrophosphate	**0.025%**	***only in claims 15, 37***
Sulfuric acid	**0.038%**	***not claimed***
EDTA	**0.05%**	***only in claims 16, 38***
Oxalic acid	0.14%	0.05 to 0.5% **any polycarboxylic acid**
Citric acid	0.9%	reads on polycarboxylic or citrate buffer
NaOH	to pH 3,7, 4.5 or 4.6	reads on adjusting pH

As can be seen from the above comparison of the scope of compositions 6, 7 and 11 and the instant claims, applicant's asserted evidence of nonobviousness is nowhere near commensurate in scope with that of the claimed subject matter. **Compositions 6, 7 and 11 are deemed allowable; however, currently there is no claim directed solely to such subject matter.** Because the claims are not sufficiently commensurate in scope with that of applicant's evidence of nonobviousness, the following grounds of rejection must be applied against the presently pending claims. These are new grounds of rejection, wherein the only new grounds are reliance on several more pages of Block's disclosure on hydrogen peroxide and pH. This new reliance is necessitated by applicant's claim amendments of 11/14/2008.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-21, 23-43, 45-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of af Ekenstam et al. (US 4,557,935) and WO 87/03779 in view of Hopkins et al (US 4,534,945), Dougherty et al. (US 5,078,672), Burke et al. (US 5,693,318) and Block.

It is noted that this ground of rejection does not apply to applicant's compositions 6, 7 and 11, which are set forth in specification Table 3. See the discussion in the preceding pages of this Office action.

af Ekenstam et al. disclose **stabilizing 0.2-5 wt% hydrogen peroxide** by **20-30 wt%** of hydrophilic lipid crystals of at least one of **1-monolaurin (C12)** and **1-monomyristin (C14)**. See column 1, lines 39-53, and claims 1-6. 1-monolaurin not only acts as a stabilizer but "also increases the germicidal power of the composition" and results in "synergism" (column 3, lines 1-9). Application to the skin is disclosed (column 3, lines 10-17). Ratio of C12 to C14 is from 3:7 to 8:2 (column 1, lines 58-60). 8:2 ratio, i.e. having more C12 than C14, provides lower viscosity (Example 8 on column 6). Stabilization is so good that the hydrogen peroxide can be stored for "several years" without any significant deterioration of germicidal activity (column 1, lines 41-44). The composition can have the consistency of an ointment and can be used on the skin (column 2, lines 57-58; column 3, lines 28-47) **or** "more liquid consistency" can be obtained by using more water and less 1-monolaurin + 1-monomyrisin mixture (column 4, Example 2). **Additional agents** such as zinc for healing, **salicylic acid** for keratolytic effect are taught (column 3, lines 31-33 and 66-68; see also claims 3 and 5). Example 1 discloses a mixture of 1-monolaurin + 1-monomyristin mixed with water, **heated to 68°C**, **cooled at a rate of 3°C per minute**,

and to the cooled, crystallized suspension was **added hydrogen peroxide** to provide 2 wt% final hydrogen peroxide concentration (column 4, lines 20-38).

WO 87/03779 is a further advancement of af Ekenstam's technology (page 1, lines 24-37). Indeed, the two documents are from the same company, Biogram. WO 87/03779 teaches an improvement wherein less 1-monolaurin and/or 1-monomyristin is used to stabilize hydrogen peroxide so that the consistency of the obtained composition is a liquid instead of an ointment (page 2, lines 12-23; page 4, lines 14-28). More specifically, 0.1-4 wt% hydrogen peroxide (0.1-2 wt% hydrogen peroxide is especially preferred) is stabilized by 0.5-15 wt% β-crystals of one or more monoglycerides of fatty acids such as 1-monolaurin and 1-monomyristin. See from page 3, line 3 to page 4, line 28; see also claims 1-11. Autocatalyzed decomposition of hydrogen peroxide is inhibited, and the hydrogen peroxide can contain normally oxidation sensitive substances such as surface active substances and others (page 2, lines 32-37). Complex forming agents such as **EDTA, citric acid (less than 2 wt%, citric is polycarboxylic), different phosphonic acids** are advantageously added, because they provide synergistic stabilizing effect with said β-crystals (see from page 4, line 29 to page 27). The composition can be made by heating the monoglyceride component with water to a temperature that is above (e.g. 5-15°C above) the transition or conversion temperature of the lipid (monoglyceride), slowly cooling to room temperature at a rate of 0.5-5°C/min to form β-crystals, and adding hydrogen peroxide (page 5, line

35 to page 6, line 37). Thickening agent such as polysaccharides, and surface active agents are taught (Examples 1 and 3).

Hopkins et al. disclose that "It is well known that the quantity of stabilizer required decreases with increasing concentration of the hydrogen peroxide" (sentence bridging columns 1-2; see also column 2, lines 2-5). Organic phosphonic compounds are "well known in the art to be stabilizers for hydrogen peroxide either with or without added tin compounds" (column 1, lines 45-48). "Tin compounds have long been known as effective stabilizers for hydrogen peroxide" (column 1, lines 62-64). Presence of phosphate stabilizer helps maintain the stability of tin-stabilized hydrogen peroxide (column 2, lines 12-14). Various phosphonic acid compounds are used with tin compound such as sodium stannate (column 2, lines 15-39). 300 mg/l tin, i.e. 0.03 wt%, is disclosed to stabilize 35% hydrogen peroxide in combination with a phosphonic acid compound (column 2, lines 23-27).

Dougherty et al. teach stabilizing hydrogen peroxide of "any convenient concentration" (column 2, lines 65-66), including 1 wt% or less, with a tin (II) salt such as **stannous oxalate** (see from column 2, line 8 to column 3, lines 27). Stannous oxalate stock solution can contain **0.5 wt% oxalic acid** (Table III, second stock solution). The stock solution can contain water and "other additives for the hydrogen peroxide, such as acids, buffers, chelating compounds, or agents to modify viscosity, surface tension" (column 2, lines 37-42) (emphases added). "One skilled in the art will

readily recognize that the most desirable amount of tin added to the solution will vary with the concentration of hydrogen peroxide, the potential for contamination of the hydrogen peroxide solution, and the intended use of the hydrogen peroxide" (column 3, lines 5-9) (emphases added).

Burke et al. disclose the well-known use of hydrogen peroxide, a topical antiseptic and antiinfective, and salicylic acid, a keratolytic, for the benefit of human health (column 1, lines 14-19). Burke et al. teach a skin care composition that contains the combination of **0.5-5% hydrogen peroxide, 0.5-5% salicylic acid**, surfactant, and phosphate ester stabilizer (see from column 1, line 53 to column 9, line 47).

Block provides a broad overview of hydrogen peroxide as a known disinfectant (pages 167-72). It is regarded as “nature’s own disinfectant and preservative” and is found in milk, honey, in the mouth (page 168, left column). Hydrogen peroxide is active against a wide variety of microorganisms; and although its activity is affected by changes in pH, with greater activity on the acid side, it is less affected than are many other commercial disinfectants (page 169, both columns). Against spores, greatest killing power is at pH 3 and the least at pH 9 for 1% hydrogen peroxide (page 169, right column). See also Tables 9-2 and 9-3 on page 170. Table 9-4 shows pH 5.0 to be better than pH 6.5 and 8.0 against four different bacteria.

The combined teachings of af Ekenstam et al. and WO 87/03779 do not expressly disclose every claimed feature set forth in the instant application claims.

However, the claimed invention as a whole would nonetheless have been obvious to one of ordinary skill in the art in view of the secondary references and the cited prior art taken as a whole.

The combined teachings of af Ekenstam et al. and WO 87/03779 does not expressly disclose 0.005-0.05 wt% or 0.01-0.03 wt% tin salt (based on tin weight) in combination with the rest of the claim-recited ingredients. However, tin compounds are well known for their stabilizing effect on hydrogen peroxide and compatibility to function with phosphate and phosphonic acid stabilizing compounds (which phosphates and phosphonic acid compounds are taught by WO 87/03779). 0.03 wt% tin is already known, albeit for 35% hydrogen peroxide; and 0.002 wt% tin, in the form of **stannous oxalate** salt is known, albeit for 6-70% hydrogen peroxide (see claim 4 of Dougherty et al.). Stannous oxalate is prepared in admixture with 0.5 wt% oxalic acid (Dougherty, Table III). Thus, the use of stannous oxalate + oxalic acid as a stabilizing component of hydrogen peroxide solution is suggestive of applicant's C_{2-6} polycarboxylic acid + tin salt components. As for the claim-specified 0.005-0.05 wt% or 0.01-0.03 wt% tin salt (based on tin weight), given the known concentration of effective amounts of tin stabilizers in other hydrogen peroxide compositions, one having ordinary skill in the art would have been able to arrive at the claimed amounts upon routine experimentation and optimization because the ordinary skilled artisan would have been quite capable of varying the amount of tin added depending on the concentration of hydrogen peroxide

and its intended use (Dougherty et al.) and also because adjusting the amount of hydrogen peroxide stabilizer with different concentration of hydrogen peroxide is well known (Hopkins et al.)

Remaining ingredients and their respective percentages/proportions are suggested by the combined teachings of the prior art taken as a whole.

Adjusting to pH 3.5 to 4.9 would have been obvious to the ordinary skilled artisan because this range of pH is well within the known effective disinfectant pH range of hydrogen peroxide (Block). For example, applicant's specification shows that the composition example in af Ekenstam's patent (the first cited reference here) has a pH of 3.5 and addition of several other ingredients maintained the pH at 3.5 – see the two compositions in applicant's specification Table 1.

Selection of lotion, spray, or cream form and adjusting the amount and ratio of the C12 and C14 monoglycerides would have been obvious from the combined teachings of af Ekenstam et al. and WO 87/03779. Using a polar surfactant having an HLB over 20 as a physical stabilizer would have been well within the skill of the ordinary skilled artisan in this field, who would have been motivated to select appropriate HLB for a surfactant to match the aqueous or oily characteristics of the ultimate composition such as a cream, emulsion or liquid. Selection of a polyacrylic acid thickener would have been obvious from the fact that polyacrylic acid type substances are well known for their thickening functionality. Retention of at least 90% hydrogen peroxide efficacy

after 2 years is suggested by af Ekenstam's teaching that storage for "several years" without significant deterioration of germicidal activity can be obtained, particularly at its optimal pH and in view of additional stabilizers that are known to function together and in the absence of contaminating hydrogen peroxide destabilizers.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

In this regard, applicant's specification data has been reviewed, but the data there is not sufficient to overcome the instant ground of rejection.

It must be noted that the tested results are nowhere near commensurate in scope with that of the claimed subject matter. See the discussion of applicant's data on page 3 of this Office action, which discussion is incorporated herein by reference to avoid repetition. Evidence of nonobviousness, if any, must be commensurate in scope with that of the claimed subject matter. In re Kulling, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990); In re Lindner, 173 USPQ 356, 358 (CCPA 1972). As a non-limiting example, results with sodium stannate does not, in the absence of additional evidence, correlate to the organometallic stannous oxalate. Additionally, only oxalic acid was tested, but the prior art suggests adding another polycarboxylic acid, citric acid. Data for oxalic acid, in the absence of additional evidence, does not correlate to a different

polycarboxylic acid such as citric acid. Moreover, even though the claims are open to 1-35 wt% monoglycerides, all the tested results are obtained with 28 wt%, which is near the high end of the range. Such tests do not indicate how the system would perform in comparison to other compositions since stability is influenced by stabilizer amounts, especially when the tested amount and the claimed amount are so far apart such as here, i.e. 28 wt% vs. 1 wt%. Further, claims read on very small amount of hydrogen peroxide ("greater than 0") but the tested compositions contained 1.15%, which is closer to the high end of the claimed range. Clearly, applicant's data is not commensurate in scope with that of the claimed subject matter, particularly in view of the fact that known stabilizers are being used to stabilize hydrogen peroxide, i.e. stabilization is expected and applicant must establish unexpected stabilization for the claimed invention as a whole, including various broad embodiments thereof.

Applicant's arguments relative hereto, filed on 11/14/2008, have been given due consideration, but they were deemed unpersuasive. Applicant argues that Block does not teach of suggest the amended pH range of the claims, pH 3.5 to 4.9. However, this pH range would have been recognized by the ordinary skilled artisan as being within the operative range for hydrogen peroxide to have its disinfecting activity. Hydrogen peroxide would have been expected to possess good disinfecting activity at pH 3.5 to 4.9; and applicant has acknowledged that af Ekenstam's stabilized hydrogen peroxide composition has a pH of 3.5. Therefore, one having ordinary skill in the art would have

had sufficient motivation to utilize the claimed pH range for the composition suggested by the combined teachings of the prior art.

Applicant also argues that a reasonable expectation of success is lacking in the rationale set forth herein. The Examiner cannot agree. Applicant seems to be under the mistaken understanding that reasonable expectation of long-term storage success, e.g. greater than 650 days to 90%, is required (see specification Table 3). In other words, applicant is confusing reasonable expectation of success for making a disinfectant that would work as a disinfectant vs. reasonable expectation of long term storage success, e.g. >650 days to 90%. However, there is nothing in the claims that requires such an expectation. All that is required is a stabilized hydrogen peroxide composition that is suitable for application to the human skin. The prior art-suggested hydrogen peroxide composition is known for such uses, is stabilized, and would be expected to have disinfecting properties. Reasonable expectation of success is found.

Applicant's arguments are found unpersuasive and this ground of rejection must be maintained.

Claims 1-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of af Ekenstam et al. (US 4,557,935) and WO 87/03779 in view of Hopkins et al (US 4,534,945), Dougherty et al. (US 5,078,672), Burke et al. (US 5,693,318), Block and Derwent abstract 1999-541010.

It is noted that this ground of rejection does not apply to applicant's compositions 6, 7 and 11, which are set forth in specification Table 3. See the discussion in beginning pages of this Office action.

Teachings of all cited references except for Derwent abstract 1999-541010 have been discussed previously in this Office action and the discussion there is incorporated herein by reference for the sake of brevity and clarity.

Derwent abstract 1999-541010 teaches that hydrogen peroxide, salicylic acid and glycerol are known to be used together for dermatological purposes, i.e. treat various skin disorders or conditions. Glycerol is disclosed to prolong the retention of the composition to the skin.

Claims 22 and 44 require the further presence of a dermatological agent such as glycerol. Although the two primary references by af Ekenstam et al. and WO 87/03779 do not specifically disclose glycerol, use of keratolytic agents has been taught and Derwent abstract 1999-541010 is further suggestive of combined use of glycerol with hydrogen peroxide and salicylic acid.

Rationale for all other claimed features from the previous ground of rejection (which did not apply Derwent abstract 1999-541010), including discussion of applicant's data, are incorporated herein by reference here. Further, it is noted that use of salicylic acid is again suggested by the teachings of the Derwent abstract cited here.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

Applicant's arguments relative to this ground of rejection are the same as the arguments made in the preceding ground of rejection under section 103. Those arguments were fully addressed in said preceding ground of rejection as being unpersuasive, and the discussion there is incorporated herein by reference.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 48 and 49 are grammatically incorrect – "said crystalline monoglyceride **has** a carbon chain length **is** selected from the group consisting of …" (emphases added).

For these reasons, all claims must be rejected again. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to John Pak whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/John Pak/
Primary Examiner, Art Unit 1616